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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/594,983	06/15/2000	William C. Olson	57906-B/JPW/SHS	8686

7590 08/25/2004

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EXAMINER	
FOLEY, SHANON A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/594,983	OLSON ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *98-104 and 117-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98-104 and 117-134* is/are rejected.

7)☒ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/3/4 and 7/26/4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

Some of the applications listed in the IDS submitted June 3, 2004 were not considered because the applications were previously abandoned and would have no bearing on the instant case. Applicant states in the submission that a copy of all of the claims from the applications listed were provided in exhibits. However, it is not clear what happened to the exhibits applicant discusses since they are unavailable to the examiner.

Claim Objections

Claim 99 is objected to because of the following informalities: the claim recites "or fragment thereof" in line 7 of the claim. There is an internal lack of antecedent basis for this "fragment". To obviate this objection, it is suggested that this phrase appear after "antibody" in line 2 of the claim. Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 98, 100-102 and 117 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 78 and 79 of copending Application No. 09/464,902.

In addition, instant claims 98, 100-102, 117, 118 and 120 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2 and 14 of copending Application No. 10/081128.

Although the conflicting claims are not identical, they are not patentably distinct from each other because there is no patentable difference between an anti-CCR5 antibody designated PA14 or another antibody that binds to the same epitope as PA14 and the instant monoclonal antibody or fragment that binds to the same epitope as PA14.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 98-103, 117, 118, 123, 124, 129 and 130 are rejected under 35 U.S.C. 102(a) as being anticipated by Wu et al. (WO 98/18826).

The claims are drawn to a monoclonal antibody or a fragment thereof comprising CDRs, where at least one CDR binds to an epitope of CCR5 in an N-terminal region

and/or one of three extracellular loops of CCR5, wherein the antibody or the fragment binds to the same epitope as one of the antibodies, such as PA14, listed in instant claim 98. The claims are also drawn to a hybridoma producing the instant antibody. The claims also specify that the antibodies are humanized or chimeric, and comprises a framework of a human immunoglobulin molecule. The claims also state that the antibody is a monovalent fragment.

Wu et al. teach that monoclonal antibodies 5C7 and 3A9 are both specific for the N-terminus of the CCR5 receptor and monoclonal antibody 2D7, which was generated from murine IgG1, has epitope specificity for the second extracellular loop of the CCR5 receptor, see page 15, lines 18-21 and page 72, line 31, and claims 1-3, 27-29, 55, and 56. The antibodies of Wu et al. comprise at least one CDR that binds to an epitope of CCR5 in an N-terminal region and/or one of three extracellular loops of CCR5, which would be the same epitopes recognized by at least one CDR in any of the instant antibodies claimed. Wu et al. also teach a bispecific antibody that binds to the N-terminus and the second extracellular loop of CCR5, see page 15, line 27 to page 16, line 5, and humanized forms of the antibodies, where the framework and the consensus are derived from a human immunoglobulin or multiple immunoglobulin molecules, where the regions surrounding the CDR regions have been replaced by human immunoglobulin molecules, see page 19, line 31 to page 21, line 32. Also see claims 1-7, 27-32, 47-50, 55 and 56.

Claims 98, 100, 101, 123 and 124 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wu et al. (J. Exper. Med. Oct. 1997; 186 (8): 1373-1381).

The claims are drawn to a monoclonal antibody that binds to the N-terminus or one of the three extracellular loops of CCR5.

Wu et al. teach a monoclonal antibody, murine IgG1 2D7, which binds to the second extracellular loop of CCR5 and another monoclonal antibody, 3A9, which binds to the N-terminal region of CCR5, see the second paragraph of the second column on page 1374 and the paragraph bridging the columns on page 1375.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 104, 119-122, 125-128 and 131-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (WO 98/18826).

The claims state that the instant antibody comprises a human immunoglobulin molecule selected from IgG1, IgG2, IgG3, IgG4, IgA and IgM.

See the teachings of Wu et al. above. Wu et al. do not teach the framework of the monoclonal antibodies to be IgG1, IgG2, IgG3, IgG4, IgA, or IgM. However, it would have been obvious for one of ordinary skill in the art at the time the invention was made to obtain the antibody framework from any of the human immunoglobulins to maintain the conformation of the CDR region and to render the recombinant antibodies less immunogenic once administered. Further, one of ordinary skill in the art would have been motivated to maintain the donor amino acid sequences immediately adjacent to the CDR domains to assure that when the framework portion of the antibody is added, the

CDR domain remains intact. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation for producing the claimed invention because humanizing antibodies using human IgG is conventional technique for humanizing recombinant antibodies. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shanon Foley
Patent Examiner, 1648